



IN THE LINE STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Denis MARTIN et al.

Serial No.: 10/650,123

Group Art Unit: 1645

Filed: August 28, 2003

Examiner: Jennifer E. GRASER

For: PHARMACEUTICAL COMPOSITIONS

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

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		Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
		No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.
Cited Ma	<u>terials</u>	
	anc	pies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) estor application Serial No, on Form 892 by the Examiner and/or Form 9 by the applicant; see 37 C.F.R. § 1.98(d).
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	Not	required by 37 CFR § 1.98.
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Respectfully submitted,

Richard M. Lebovitz, Reg. No. 37,067

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Attorney Docket No.: IDB-0033

Date: January 13, 2006

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Substitute	for form 1449A/PT	0			Complete if Known	
				Application Number	10/650,123	
INFO	RMATION	DISC	CLOSURE	Filing Date	August 28, 2003	
STAT	EMENT B	Y AP	PLICANT	First Named Inventor	Denis MARTIN et al.	
				Group Art Unit	1645	
	(use as many sh	eets as n	ecessary)	Examiner Name	Jennifer E. GRASER	
Sheet	1	of	3	Attorney Docket Number	IDB-0033	

	U.S. PATENT DOCUMENTS				
Examiner Initials *	Cite No.1	U.S. Patent Docur	ment Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
	1	6,287,574		Bernard BRODEUR et al.	09-11-2001

Examiner Initials*	Cite No.1	Foreign Patent Document			Date of Publication of	Pages, Columns, Lines, Where Relevant		
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	2	wo	99/52549		Martin FRIEDE et al.	10-21-1999		

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Substitute for form 1449A/PTO Complete if Known **Application Number** 10/650,123 INFORMATION DISCLOSURE August 28, 2003 Filing Date STATEMENT BY APPLICANT First Named Inventor Denis MARTIN et al. 1645 Group Art Unit (use as many sheets as necessary) Jennifer E. GRASER **Examiner Name** Sheet of Attorney Docket Number IDB-0033

	1	NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Τ²
		Martin et al.; "Highly Conserved <i>Neisseria meningitidis</i> Surface Protein Confers Protection against Experimental Infection," J. Exp. Med, 7 April 1997, pages 1173-1183, Vol. 185, no. 7.	
	4	Martin et al. "Candidate Neisseria meningitidis NspA vaccine," Journal of Biotechnology, 83 (2000) 27-31.	
	5	Carmenate et al.; Recombinant Opc protein from <i>Neisseria meningitidis</i> reconstituted into liposomes elicits opsonic antibodies following immunization; Biotechnol. Appl Biochem (2001) 34, 63-69	
	6	Christodoulides et al.; Immunization with recombinant class 1 outer-membrane protein from <i>Neisseria meningitidis</i> : influence of liposomes and adjuvants on antibody avidity, recognition of native protein and the induction of a bactericidal immune response against meningococci; Microbiology (1998) 144, 3027-3037; XP-002271046	
	7	Martin et al.; Recombinant NspA incorporated into liposomal vesicles induces functional antibodies; Vaccine Research Unit, Laval University Medical Center, Ste-Foy, Quebec, Canada	
	8	Sacchi et al.; Considerations on the use of <i>Neisseria meningitidis</i> class 5 proteins as meningococcal BC vaccine components; Vaccine, 1995, Volume 13, Number 1, pp. 112-118	
	9	Tinsley et al.; Antibodies recognizing a variety of different structural motifs on meningococcal Lip antigen fail to demonstrate bactericidal activity; Journal of General Microbiology (1992), 138, 2321-2328	
	10	Moe et al.; Functional Activity of Anti-Neisserial Surface Protein A Monoclonal Antibodies against Strains of <i>Neisseria meningitidis</i> Serogroup B; Infection and Immunity, June 2001, pp. 3762-3771	
	11	Hou et al.; Conformational Epitopes Recognized by Protective Anti-Neisserial Surface Protein A Antibodies; Infection and Immunity, Dec. 2003, pp. 6844-6849, vol. 71, no. 12.	
•	12	Vandeputte-Rutten et al.; Crystal Structure of Neisserial Surface Protein A (NspA), a Conserved Outer Membrane Protein with Vaccine Potential; Journal of Biological Chemistry; Vol. 278, No. 27, Issue of July 4, pp 24825-24830, 2003	
	13	Moe et al.; Sequential Immunization with Vesicles Prepared from Heterologous Neisseria meningitidis Strains Elicits Broadly Protective Serum Antibodies to Group B Strains; Infection and Immunity, Nov. 2002, p 6021-6031, vol. 70, no. 11.	
	14	Koroev et al., Induction of Antimeningitis Immunity by Synthetic Peptides: III. Immunoactive Synthetic Fragments of the NspA Protein from <i>Neisseria meningitidis</i> ; Russian Journal of Bioorganic Chemistry, Vol. 28, No. 4, 2002, pp. 263-268	
	15	Arigita et al.; Restored functional immunogenicity of purified meningococcal PorA by incorporation into liposomes; Vaccine 21 (2003) 950-960	
	16	Wright et al.; Immunization with the Recombinant PorB Outer Membrane Protein Induces a Bactericidal Immune Response against Neisseria meningitidis; Infection and Immunity, Aug. 2002, pp. 4028-4034, vol. 70, no. 8.	

17	Arigita et al.; Liposomal Meningococcal B Vaccination: Role of Dendritic Cell Targeting in the Development of a Protective Immune Response; Infection and Immunity, Sept. 2003, p. 5210-5218, vol. 71, no. 9.
18	Jolley et al.; Immunization with Recombinant Opc Outer Membrane Protein from Neisseria meningitidis: Influence of Sequence Variation and Levels of Expression on the Bactericidal Immune Response against Meningococci; Infection and Immunity, June 2001, p. 3809-3916, vol. 69, no. 6.
19	Idanpaan-Heikkila et al.; The antibody response to a prototype liposome vaccine containing Neisseria meningitidis outer membrane protein P1 produced in Bacillus subtilis; Vaccine, Vol. 13, No. 16, pp. 1501-1508, 1995.
20	Parmar et al.; Biophysical and antigenic characterization of gonococcal protein I incorporated into liposomes; Vaccine, Vol. 15, no. 15, pp. 1641-1651, 1997
21	Niebla et al.; Immunogenicity of recombinant class 1 protein from <i>Neisseria meningitidis</i> refolded into phospholipids vesicles and detergent; Vaccine 19 (2001) 3568-3574
22	Ward et al.; Expression of <i>Neisseria meningitidis</i> class 1 porin as a fusion protein in <i>Escherichia coli</i> : the influence of liposomes and adjuvants on the production of a bactericidal immune response; Microbial Pathogenesis 1996; 21: 499-512
23	Morley et al.; Vaccine prevention of meningococcal disease, coming soon?; Vaccine 20 (2002) 666-687
24	Vermont et al.; Recent developments in vaccines to prevent meningococcal serogroup B infections; Current Opinion in Molecular Therapeutics, 2003, 5(1): 33-38
25	Bethell et al.; Meningococcal vaccines; Expert Rev. vaccines, 1(1), 75-84 (2002)
26	Rosenqvist et al.; The 5C Protein of <i>Neisseria meningitidis</i> Is Highly Immunogenic in Humans and Induces Bactericidal Antibodies; The Journal of Infectious Diseases 1993; 167:1065-73

Examiner Signature		Date Considered		$\Big]$
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